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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,195	06/26/2003	Jordi Xaus Pey	HERR 20.471	7599

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KATTEN MUCHIN ZAVIS ROSENMAN  
575 MADISON AVENUE  
NEW YORK, NY 10022-2585

EXAMINER
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AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/609,195	XAUS PEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Vera Afremova	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 13-38 is/are rejected.
- 7) ☐ Claim(s) 16-38 is/are objected to.
- 8) ☐ Claim(s) 1-38 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-38 are pending.

#### ***Claim Objections***

Claims 16-38 are objected to under 37 CFR 1.75(c) as being in improper form because of multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 16-32 cannot be properly further treated on the merits.

#### ***Claim Rejections - 35 USC § 112***

Claims 13-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-32 are indefinite because components of the compositions as claimed cannot be reasonably determined. It is uncertain what strains and what products derived from strains are included in the claimed mixed compositions particularly in view that the products as claimed are unidentified compounds including supernatants, extracts and/or "metabolic activity" (claims 21-32).

With respect to claims 16, 17, 26 and 28 it is noted that a broad range or limitation together with a narrow range or limitation falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether

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the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims recite the broad recitation about using “2-6 strains”, 0.1%-99.9% or broad ranges of CFU, and the claims also recite some lower number of strains, some narrower percent ranges and some narrower CFU ranges that are narrower statements of the prior ranges/limitations.

Claims 13-15 provide for the use of milk and/or amniotic fluid and Claims 33-38 provide for the use of bacterial stains and bacterial products, but, since the claims 13-15 and 33-38 do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13-15 and 33-38 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a method for the selection of probiotic microbial strains capable of surviving in breast milk and/or amniotic fluid, classified in class 435, subclass 29, for example.

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- II. Claim(s) 6, drawn to a bacterial strain capable of surviving in breast milk and/or amniotic fluid, classified in class 435, subclass 252.1, for example.
- III. Claims 7-12, drawn to particular *Lactobacillus* strains, classified in class 435, subclass 252.8, for example.
- IV. Claims 13-15, drawn to a method of using milk and/or amniotic fluid for selecting probiotic bacteria, classified in class 435, subclasses 34, for example.
- V. Claims 21-23, drawn to unidentified compound(s) derived from bacterial strain(s), classified in class 424, subclasses 114 and/or 115, for example.
- VI. Claims 16-20 and 24-32, drawn to mixed bacterial products of unidentified contents, classified in class 435, subclass 252.4, for example.
- VII. Claims 33-38, drawn to a method of using bacteria and products derived from bacteria for making bacterial compositions intended for various therapeutic treatments, classified in class 424, subclass 93.3, for example.

The inventions are distinct, each from the other because of the following reasons:

The products of Groups II, III, V and VI are distinct products as claimed because they have different components having different characteristics as claimed. The product of Group V is a compound derived and/or separated from bacteria. The Group II and the Group III products are different bacteria having different characteristics as claimed. The Group VI product is an intentional mixture of various strains and products thereof.

The methods of Groups I, IV and VII are distinct as claimed because they comprises and/or encompass different active steps of manipulating different elements or components as claimed. The Group I method is a selection/testing method. The Group VII method is a method

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for manufacturing compositions comprising the preselected strains and/or products thereof. The Group II method encompasses the use of milk and/or amniotic fluid for making the selection culture media.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other microbial product such as, for example, non-pathogenic yeast *Saccharomyces* that is materially different from a bacterial strain product that is required for the Group II product.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

January 28, 2005



VERA AFREMOVA

PRIMARY EXAMINER